#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/603,094

Applicant : Don J. DIAMOND Filed : June 25, 2003

TC/A.U. : 1648

Examiner : Louise Wang Zhiying HUMPHREY

Docket No. : 1954-410 Customer No. : 06449 Confirmation No. : 7356

## **DECLARATION UNDER 37 C.F.R. §1.132**

Director of the United States Patent and Trademark Office P.O. Box 1450 Alexandria, Virginia 22313-1450

Dear Sir:

- I, Dr. Don J. Diamond, do solemnly declare that:
- 1. I am of mature age and competent to make this declaration.
- 2. I am the same Don J. Diamond listed as an inventor on the abovereferenced patent application.
- 3. I received an A.B., magna cum laude, in biology from Harvard University in 1977 and a Ph.D. in biological chemistry from Harvard Medical School in 1984. I did post-doctoral training in the Pathology Department of Harvard Medical School and at the Dana-Farber Cancer Institute. In 1988, I became an instructor in Pathology at Harvard Medical School and the Dana-Farber Cancer Institute. In 1989, I began work as an assistant research scientist at the Beckman Research Institute of the City of

Hope, Duarte, California. I have since been promoted to the position of Professor of Virology and Head of the Laboratory of Vaccine Research there. Since coming to the City of Hope, a major focus of my research has been in the field of peptide vaccines. A copy of my curriculum vitae is attached herewith as Exhibit 1.

- 4. I have reviewed and am familiar with U.S. Patent Application Serial No. 10/603,094 filed June 25, 2003, entitled "Adjuvant-Free Peptide Vaccine," including the claims currently pending on the application. I also have reviewed and am familiar with the Office Action dated November 29, 2007 and the references cited therein.
- 5. The Zaia reference, which was co-authored by me, describes the use of lipidated peptides as vaccines. At the time this application was filed, peptide vaccines were considered not to possess immunogenic activity or to function effectively as a vaccine unless lipidated or administered with a harsh, inflammatory adjuvant such as alum or Freund's adjuvant. Because these types of adjuvants are not suitable for use in humans, lipidation was required for the vaccine to function. This thinking is reflected in the Zaia reference, which describes lipidated vaccine peptides and refers to the inactivity of peptides in which the lipid chains are too short. The Zaia reference does not refer to unlipidated peptide vaccines as active and does not guide the reader to remove the lipid moiety since this was considered essential to its function. Therefore, it is my opinion that the Zaia reference does not disclose to the skilled person any unlipidated vaccine peptides and particularly that the Zaia reference does not disclose the vaccines and peptides claimed in this patent application.
- 6. Since the Zaia reference teaches that long lipid chains are required for peptide vaccine activity (see Zaia, page 351, left column, lines 22-24), it also is my

opinion that this reference does not suggest the claimed invention to the skilled person and does not guide one to make unlipidated peptide vaccines. Furthermore, it is my opinion that the skilled reader would not take away from Zaia a reasonable expectation that an unlipidated peptide vaccine would have appropriate activity or would function as a vaccine.

- 7. The Krieg reference discusses DNA adjuvants as general immune stimulants and does not discuss fusion peptide vaccines as claimed here or make up for the lack of teaching with respect to unlipidated peptide vaccines in Zaia.
- 8. In summary, it is my opinion that the teachings of Zaia, even when combined with Krieg, do not teach or render obvious an unlipidated peptide as is claimed here.
- 9. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dr. Don J/Diamond

Date

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#### **CURRICULUM VITAE**

Don J. Diamond, Ph.D.

Current Address: Beckman Research Institute of the City of Hope

Laboratory of Vaccine Research Fox Plaza South. Rm 1000B

1500 E. Duarte Road Duarte, California 91010

**Voice**: 626-256-4673 x63450

**Fax:** 626-301-8981

email: ddiamond@coh.org

Date of Birth: February 20, 1955 Location: Bethlehem, Pa.

**Present Position:** 

10/99-Present Professor of Virology and Head, Laboratory of Vaccine Research

Education:

9/73-6/77 A.B. in Biology (Magna C.L.), Harvard University, Cambridge, MA. Candidate in Biochemistry and Biophysics, UCSF Medical School,

Laboratory of Howard M. Goodman, Ph.D., San Francisco, CA.

9/81-9/84 Ph.D., Department of Biological Chemistry, Harvard Medical School

and Massachusetts General Hospital in the Laboratory of Howard

M. Goodman, Ph.D., Boston, MA.

**Previous Positions:** 

10/94-9/99 Associate Research Scientist, Department of Hematology

Research

3/89-9/94 Assistant Research Scientist and Section Head of Immunobiology,

Beckman Research Institute of the City of Hope, Duarte, CA.

7/88-2/89 Instructor in Pathology, Harvard Medical School, Boston, MA.

3/86-6/88 Research Fellow in Pathology, Harvard Medical School, Boston,

MA.

3/86-2/89 Postdoctoral Fellow, Dana Farber Cancer Institute in the Laboratory

of Immunobiology (E. Reinherz), Boston, MA.

10/84-2/86 Postdoctoral Fellow in the Center for Cancer Research.

Massachusetts Institute of Technology (Laboratory of S.

Tonegawa), Cambridge MA.

2/78-8/79 Research Associate, E.M.B.L. in the Laboratory of H. Lehrach,

Heidelberg, F.R.G.

**Awards and Honors:** 

1977 Summa Cum Laude Thesis in Biology, "Identification of a

	Precursor for Globin mRNA", Laboratory of P. Doty, Ph.D.
7/85-6/87	Fellow of the Leukemia Society of America
2/94	Ad-Hoc Reviewer, Grants in Aid, American Heart Association,
2,01	Los Angeles Chapter
10/95-1/03	Vice Chair, City of Hope "Institutional Biosafety Committee"
6/97	NIH-PO1 Review Panel "Dendritic Cell-Based Vaccines:
	Experimental and Clinical Studies", U. of Michigan Medical Center,
11/97-present	Member, Scientific Review Committee, Concern Foundation, Los
•	Angeles, CA
12/97-present	Ad-hoc Reviewer, Journal of Immunology
12/97-present	Ad-hoc Reviewer, Cancer Research
4/01-present	Ad-hoc Reviewer, Journal of Infectious Diseases
8/01-present	Ad-hoc Reviewer, BLOOD
8/03-present	Ad-hoc Reviewer, Experimental Hematology
11/98	Special Review Panel, "NCI/Innovative Technology for the
	Molecular Analysis of Cancer", Rockville, MD
11/99 - present	Military Infectious Disease Research Program of the DOD and
	USAMRMC External Review Panel "HIV Vaccines" and Consultant
	to AIBS
7/00	Member of DOD Prostate Cancer Immunol. Sciences Study Section
4/01	NCI-RAID 6 <sup>th</sup> Cycle Review Panel Member-Frederick, MD.
6/01	NIH-PO1 Review Panel "The Immunobiology of Marrow Allografts
	for Leukemia", Memorial Sloan Kettering Medical Center,
0.10.4	R.O'Reilly, M.D., P.I.
9/01	NIH-NIAID Special Emphasis Review Panel ZAI1-RCG-M-C2"
10/01	"Evaluation of control measures for diseases other than AIDS" Invited Review from Health Research Council of Canada
4/02	BSF Review Panel, "Study of Antigen Presentation in Melanoma, Y.
4/02	Reiter and S.A. Rosenberg, P.I.
6/02	Invited Plenary Speaker, ASGT, Annual Meeting
7/02-present	Wellcome Trust Grant Review, V. Emery P.I.
8/02	Invited speaker to ACS 224 <sup>th</sup> Annual Meeting, Boston, MA
10/02	NIH-PO1 Review Panel, Duke UMC "Immunotherapy With High
10/02	Frequency, CEA Specific T cells." K. Lyerly, Pl.
11/02-present	Review Committee for Flight Attendant Medical Research Institute
7/02-present	USAMRMC Bio-Defense Project Reviewer
1/03	NIAID-SEP review of IPCAVD/HIVRAD
8/03	Appointed to Beckman Foundation Review of Tetramer Initiative.
9/03	NIAID-SEP Panel ZAI1 ALR-M (J2)
12/03	NIAID-SEP Panel ZRG1 VACC (06)
2/25/04-present	NCI Appointed Panel Reviewer for Cancer Immunotherapy (CII
•	Study Section)
3/22/04	Chair, HIVRAD/NIAID Review Panel
12/06/04	Moderator, Simultaneous Session "Infections" Annual Meeting,
	ASH, San Diego, CA
4/05	Appointed to the International Organizing Committee, 10 <sup>th</sup> CMV

Workshop; Invited Plenary Talk; Round-Table Discussion Leader on Prospects for a CMV Vaccine, S. Plotkin, M.D., moderator,

Williamsburg, VA.

1/06 Chair, Partnership for HCV Vaccine Development (RFA NIH-NIAID-

DMID-05-030), Washington, DC

2/06 HIVRAD/NIAID Review Panel

6/06-6/07 VMD-IRG Review Panel, ad hoc membership.

8/06 Editorial Board Member, Recent Patents on Anti-infective Drug

Discovery, Bentham Science Publishers Ltd.

7/07 Appointed to 4 year term on NIH Study Section "Vaccines for

Microbial Diseases"

11/2007 Chair of 2007 IPCAVD

Active INDs: BB-IND #13124 approved on 9/29/06 "CMV Fusion Peptide"

(PADRE T-cell helper epitope and Tetanus T-cell helper epitope;

synthetic; Bachem California) Vaccine with and without Oligodeoxynucleotide Immunomodulator (CPG 7909; Coley

Pharmaceutical Group, Inc)"

## **Previous Funding:**

4/90-2/94	National Cancer Institute, "IFN-γ Expression in Leukemic and
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Activated T cells", PI, CA-52177, Direct Costs, \$350,000.

7/91-7/92 Rheumatic Disease Research Foundation, "Clinical Applications

of a Soluble Antigen-Specific T Cell Receptor: A Reagent for

Studying Auto-immunity, PI, Direct Costs, \$50,000.

10/92-3/95 National Cancer Institute, "Bone Marrow Transplantation For

Hematologic Malignancy", PO1CA30206, Stephen Forman, M.D., PI, Don J. Diamond, Ph.D., Co-PI Project II, "The Antigen

Specific Immune Responses to HCMV", Annual Direct

Costs,\$64,290.

10/92-3/95 National Cancer Institute, "Bone Marrow Transplantation For

Hematologic Malignancy", PO1CA30206, Stephen Forman, M.D., PI, Don J. Diamond, Ph.D., PI, Project V, "Identification of T Cell Receptor Variable Gene Segments Associated with the Clinical Course of GVHD in Recipients of Allogeneic Bone Marrow

Transplants", Annual Direct Costs, \$90,584.

6/98 H.N. and Frances C. Berger Foundation, Purchase of Flow

Cytometer, Grant#98-34, Don J. Diamond, Ph.D., Pl, Annual Direct

Costs, \$100,000.

4/95-2/00 National Cancer Institute, "Bone Marrow Transplantation For

Hematologic Malignancy", PO1CA30206, Stephen Forman, M.D., PI, Don J. Diamond, Ph.D., PI, Project IV, "Acquisition of Immunity to CMV", 30% Effort, Annual Direct Costs, \$178,703.

4/95-2/00	National Cancer Institute, "Bone Marrow Transplantation For Hematologic Malignancy", PO1CA30206, Stephen Forman, M.D., PI, Don J. Diamond, Ph.D., Co-Investigator, Project I, "Allogeneic Bone Marrow Transplantation for Hematologic Malignancy", 7% Effort, Annual Direct Costs, \$104,108.
7/97-6/02	National Cancer Institute, "p53 Directed Immunotherapy of Breast Cancer", R29CA70819, J. Ellenhorn, PI. Don J. Diamond, Consultant, Annual Direct Costs, \$72,000.
10/98-9/02	National Institute of Health, "Lipopeptide Vaccination Against AIDS in Patients Undergoing HAART", R21AI44313, Innovation Grant Program for Approaches in HIV Vaccine Research, Don J. Diamond, Ph.D., PI, 10% Effort, Annual Direct Costs, \$150,000.
6/99 - 5/02	National Institute of Health, "Vaccination for CMV in AIDS Patients Undergoing HAART", ROI A143267-S1, Research Supplement for Under-Represented Minorities, Don J. Diamond, Ph.D., P.I., No Effort, Annual Direct Costs, \$40,856
9/97 – 8/02	Leukemia Society of America, "Therapeutic Vaccine to Limit CMV Infection After BMT", LSA 6116-98, Don J. Diamond, Ph.D., P.I., 10% Effort, Annual Direct Costs \$100,000
10/00 –12/02	National Cancer Institute, "Preclinical Evaluation of Mono- and dilapidated Vaccines for Activity Against Cytomegalovirus", Subcontract 20XS192A, Don J. Diamond, Ph.D., P.I. 10% Effort, Annual Direct Costs \$98,927
9/92 – 6/02	National Institute of Health,"Clinical Oncology Research Career Development Program" 5 K12 CA01727-10, Don J. Diamond, Ph.D., P.I., 2.5% Effort, No salary.
6/98-5/03	National Institute of Health, "Vaccination for CMV in AIDS Patients Undergoing HAART", RO1AI43267, Don J. Diamond, Ph.D., PI, 20% Effort, Annual Direct Costs, \$275,361.
4/98-3/04	National Cancer Institute, "Lipopeptide Vaccine to Prevent HCMV Infection after BMT," R01 CA77544, Don J. Diamond, Ph.D., PI, 20% Effort, Annual Direct Costs \$285,359
11/02-4/04	University of California AIDS Research Program, "Ubiquitin Targeting to Enhance Immune Response to HIV Antigen," ID02-BRI-054, Don J. Diamond, Ph.D., PI, 10% Effort, Annual Direct Costs \$100,200.
9/01-8/04	The Leukemia and Lymphoma Society, "HLA Tetramer-Guided Analysis of CMV Immunity After BMT," LLS 6122-02, Don J. Diamond, Ph.D., Consultant, No Effort, Annual Direct Costs, \$100,000.
5/03 – 4/05	NIH-NCI, "Early Therapeutics Development with Phase II Emphasis", Sub-contract 23XS021, David R. Gandara, M.D., P.I., Don J. Diamond, Ph.D., Co-investigator, 2.5% Effort, Annual Direct Costs \$36,800.
6/04-9/05	NCI-SAIC-Frederick, "Design of an <i>in vivo</i> Assay to Measure the Potency of the PADRE-CMV and Tetanus-CMV Peptides," Sub-

3/00–11/05	contract 24XS044, Don J. Diamond, Ph.D., PI, 5% Effort, \$95,345. NCI, "Hematopoietic Cell Transplantation for Hematologic Malignancy" Project III "Acquisition of Immunity to CMV" PO1 CA30206, Don J. Diamond, PhD, PI of Project III, 15% Effort, Annual Direct Costs \$213,226.
4/02-5/06	NIH, "HCV and Progression of HIV and HAART Response in Women", R01-Al52065-04, Andrea Kovacs, M.D., PI, Don J. Diamond, Ph.D., Co-Investigator, 5% Effort, Annual Direct Costs, \$9,785.
4/04-3/06	NIH-NCI, "Cellular Immunity to BK Virus", R21-CA104261, Don J. Diamond, Ph.D., Co-Investigator, 5% Effort, Annual Direct Costs Year 1, \$100,000.
11/98-12/06	NCI-RAID, "Development of a GMP-Manufacturing Strategy and Acquisition of Clinical-Grade Quantities of a Lipopeptide Vaccine with Activity Against Cytomegalovirus", Don J. Diamond, Ph.D., P.I., Project Costs, \$600,000.
10/05-02/07	NCI-SAIC-Frederick, "GLP Production of p53-MVA as Seed Stock for GMP Production", 25XS061, Don J. Diamond, Ph.D., PI, 5% Effort, Annual Direct Costs, \$69,928.
10/04-09/07	LLS, "HLA Tetramer-Guided Analysis of CMV Immunity after HCT," R6145-05, Simon F. Lacey, Ph.D., Pl, Don J. Diamond, Ph.D., Co-Investigator, 5% Effort, Annual Direct Costs, \$130,000.
11/05-02/07	NCI-RAID, "A Modified Vaccinia Virus Ankara Targeting p53 in Breast Cancer", Joshua D. I. Ellenhorn, MD, PI, Don J. Diamond, Ph.D., Consultant, Project Costs, \$600,000.

# **Current Funding**

12/05-11/10	NIH-NCI, "Hematopoietic Cell Transplantation for Hematologic Malignancy", PO1-CA30206-24A1, Project III "Vaccine-Induced Immunity to CMV", Don J. Diamond, Ph.D., Project PI, 20% Effort, Annual Direct Costs Year 25, \$435,000.
3/04-3/09	National Cancer Institute, "Peptide Vaccine to Prevent CMV Disease after HSCT", RO1-CA77544-09, Don J. Diamond, Ph.D., PI, 20% Effort, Annual Direct Costs Year 7, \$276,000.
4/05-3/09	NIH-NCI, "Peptide Vaccine to Prevent HCMV Infection after HSCT" Research Supplement for CA77544-06, Don J. Diamond, Ph.D., PI, 0% Effort, Annual Direct Costs Year 1, \$61,601.
7/04-6/08	NIH, "Evaluation New Targets of CMV Cellular Immunity, R01-AI0581148-01A1, John A. Zaia, M.D., PI, Don J. Diamond, Ph.D., Co-Investigator, 5% Effort, Annual Direct Costs, \$250,000.
7/05-6/08	FAMRI, "An MVA Vaccine Targeting p53 in Breast Cancer",

	042275, Joshua D. I. Ellenhorn, MD, PI, Don J. Diamond, Ph.D., Consultant, Annual Direct Costs Year 3, \$100,000.
4/05-3/08	NIH-NIAID "CpG DNA:Epitope Fusion Peptide Conjugates as HIV Vaccines" 1 R21 Al062496-01A1, Don J. Diamond, Ph.D., Pl, 5% Effort, Total Direct Costs, \$137,500.
4/05-3/08	NIH-NCI, "Clinical Evaluation of a Poxvirus Vaccine Targeting p53", 1 R21 CA114889-01, Joshua D. I. Ellenhorn, MD, PI, Don J. Diamond, Ph.D., Co-Investigator, 10% Effort, Annual Direct Costs Year 1, \$177,000.
9/07-8/09	NCI-RAID, "Recombinant Modified Vaccinia Ankara Expressing CMV Antigens for use in Stem Cell Transplantation for Hematologic Malignancy", Don J. Diamond, Ph.D., PI, Project Costs, TBD.
7/07-6/10	NIH-NCI, "Molecular Diagnosis of Defective Memory Differentiation in Tumor-Specific T Cells," R21 CA129670-01, Nicholas Haining, PhD, PI, Don J. Diamond, PhD, Co-Investigator, 5% Effort, Annual Direct Costs Year 01, \$142,250.
12/07-11/09	NCI-SAIC-Frederick, "GLP Production of CMV-MVA as Seed Stock for GMP Production", 28XS023, Don J. Diamond, Ph.D., PI, 5% Effort, Annual Direct Costs, \$112,662.

## **PENDING**

7/01/08-6/30/13 NIH-NIAID, "Therapeutic Vaccines for CMV Evaluated in a

Nonhuman Primate Model" R01 Al079559-01, Peter Barry, PhD, Pl, Don J. Diamond, PhD, Co-PD/Pl, 10% Effort, Annual Direct Costs

Year 01 for COH site, \$240,517.

## Pre- and Postdoctoral Scientist Trainees (1989-Present):

- Dr. David Brown, NRSA Senior Fellow (1990-91)
- Dr. Anne Buchwalder (1990-1992)
- Dr. Lee Slice (1992-1993)
- Dr. Daniel Pang, (1992-1994)
- Dr. Takuya Tsunoda, (1993-1995), now at Wakayama Medical School (Assistant Professor), Wakayama, Japan
- Dr. Xiping Liu, (1993-2000), now at Mann-Kind Inc., Valencia, CA.
- Dr. Malcolm Barth, (1995-1996)
- Dr. Vera Chesnokova, (1994-1996), now assistant faculty at UCLA Medical School
- Dr. Jiyao Sun, (1996-1998), now Assistant Director, HLA Services, Dept. of

Hematology, City of Hope National Medical Center

- Dr. Todd McCarty, (1996-1997, ACS Fellow), Baylor University affiliated hospitals
- Dr. Corinna LaRosa, (1997-Present)
- Dr. Mi-Heon Lee, (1997-1999), now in the Department of NeuroSciences, City of Hope
- Dr. L. BenMohammed, (1997-1999), now Assistant Professor, UC Irvine, Irvine, CA.
- Dr. Simon Lacey, (1998-Present)
- Dr. Michel Denis, (1998-1999)
- Dr. Ming Zhang, (1998-1999), now in the Department of Immunology, Amgen Inc.
- Dr. Radhika Krishnan, (1998-9/2000)
- Dr. John Simms (1999-2001), now at CTL Inc., Chatsworth, CA
- Dr. Maria Villacres (1999 –2002), now an Assistant Professor, USC Keck School of Medicine, Los Angeles CA
- Dr. Zhongde Wang (2000 Present)
- Dr. Rahul Sharan (2001-2002), now at Polypeptide Laboratories, Torrance CA.
- Dr. Pirouz Daftarian (2002-2004), now at University of Miami, Florida.
- Dr. Guang-Yun Song (2003-Present)
- Dr. Wahajul Hag (2003-2004), now at Central Drug Research Institute, Lucknow, India.
- Ms. Tamineh Yazdi (2004-2007)
- Dr. Angelo Mandarino (2004-2005)
- Dr. Ludmilla Krymskaya (2004), now at Mann-Kind Inc., Valencia, CA.
- Dr. Tumul Srivastava, (2006-Present)
- Dr. Wendi Zhou (2005-Present)
- Dr. Aprille Matthews (2005-Present)
- Dr. Jinliang Li (2006-Present)
- Dr. Scott Fisher (2006-Present)
- Dr. Ravindra Rawal (2007-Present)
- Dr. Hidenobu Ishizaka (2007-Present)

## **Original Papers**

- 1. **Diamond DJ** Studies at the scute locus of Drosophila melanogaster. <u>Seccan News</u> Magazine, 4: 1-4 (1973).
- 2. Lehrach H, **Diamond DJ**, Wozney JM, and Boedtker H. RNA molecular weight determination by gel electrophoresis under denaturing conditions: A critical reexamination. Biochemistry, 16: 4743-4750 (1977).

- 3. Cordell B, **Diamond DJ**, Smith S, Punter J., Schone H.H., and Goodman, H.M. Disproportionate expression of the two non-allelic rat insulin genes of a pancreatic tumor is due to translational control. <u>Cell</u>, 31: 531-542 (1982).
- 4. Goodman HM, Berg P, Clark S, Cordell B, **Diamond DJ**, Nguyen-Huu C, Kan YW, and Lebo RV. Structure, evolution and expression of mammalian insulin genes. In: Schmitt, F.O., Bird, S.J., and Bloom, F.E. (eds.), <u>Molecular Genetic Neuroscience</u>, pp.103-115. New York: Raven Press (1982).
- 5. Moore DD, Walker MD, **Diamond DJ**, Conkling MA, and Goodman HM. Structure, expression and evolution of growth hormone genes. <u>Rec. Prog. Hor. Res.</u>38: 198-225 (1982).
- 6. Fukata J, **Diamond DJ**, and Martin JB. Effects of rat growth hormone releasing factor and somatostatin on the release and synthesis of rGH in dispersed pituitarycells. <u>Endocrin</u>, 117: 457-467 (1985).
- 7. **Diamond DJ** and Goodman HM. Regulation of growth hormone mRNA synthesis by dexamethasone and triiodothyronine: Transcriptional rate and mRNA stability changes in pituitary tumor cells. <u>J. of Mol. Biol.</u> 181: 41-62 (1985).
- 8. Hayday AC, **Diamond DJ**, Tanigawa G, Heilig JS, Folsom V, Saito H, and Tonegawa S. Unusual organization and diversity of T cell receptor alpha chain genes. <u>Nature</u> (London) 316, 828-830 (1985).
- 9. Clayton LK, Ramachandran H, Pravtcheva D, Chen Y, **Diamond DJ**, and Reinherz EL. The gene for T11 (CD2) maps to chromosome 1 in humans and to chromosome 3 in Mice. J. of Immunol. 140:361-367 (1988).
- 10. **Diamond DJ,** Clayton LK, Sayre PH, and Reinherz EL. Exon-intron organization and sequence comparison of human and murine T11 (CD2) genes. Proc. Natl. Acad. Sci. USA, 85:1615-1619 (1988).
- 11. **Diamond DJ**, Nelson FB, and Reinherz EL. Lineage-Specific Expression of a T-Cell Receptor Variable Gene Promoter Controlled By Upstream Sequences. <u>J. of Exp. Med</u>., 169:1213-1231 (1989).
- 12. Brown D, Nelson FB, Reinherz EL, and **Diamond DJ.** The human Interferon-gene contains an inducible promoter that can be transactivated by Tax I and II. <u>European J. of Immunology</u>, 21: 1879-1885 (1991).
- 13. **Diamond DJ**, Siliciano RF, Szalay P, Symer P, Hao P, Reinherz EL, and Dintzis HM. MHC independent T cell receptor-antigen interaction: Functional analysis using fluorescein derivatives. J. of Exp. Med., 174: 229-241 (1991).

- 14. Brown D, Kondo K, and **Diamond DJ.** Characterization of nuclear protein binding to the Interferon-( promoter in quiescent and activated human T cells, <u>Eur. J. of Immunol.</u>, <u>22</u>: 2419-2428 (1992).
- Symer DE, Dintzis RZ, Diamond DJ, and Dintzis HM. Activation and inhibition of human T cell receptor transfectants by defined soluble antigen arrays.
   J. of Expt. Med. 176: 1421-1430 (1992).
- 16. Buchwalder A, Krangel M, Hao P, **Diamond DJ.** Direct binding of Antigen to Lipid anchored and soluble forms of an MHC independent human  $\alpha/\beta$  T cell receptor, Molecular Immunology, 31: 857-872 (1994).
- 17. **Diamond DJ**, Chang KL, Jenkins KA, and Forman SJ. Immunohistochemical analysis of T cell phenotypes in patients with graft versus host disease following allogeneic bone marrow transplantation. <u>Transplantation</u>, <u>59</u>: 1436-1444 (1995).
- 18. Liu X, Chesnokova V, Forman SJ and **Diamond DJ.** Molecular analysis of T cell Receptor repertoire in bone marrow transplant recipients: evidence for oligoclonal T cell expansion in GVHD lesions. <u>Blood</u>, <u>87</u>: 3032-3044 (1996).
- 19. Ellenhorn JDI, Yu Z, **Diamond DJ.** Generation of p53 specific and HLA restricted cytolytic T lymphocytes using recombinant vaccinia virus and HLA transgenic mice. Owen H. Wangensteen Surgical Forum, 47: 503-505, (1996).
- 20. Liu X, Chesnokova V, Forman SJ and **Diamond DJ.** Methods for determining expression and oligoclonality of TCRs in GVHD lesions from allogeneic BMT recipients. In:Oksenberg, J. R. (ed). The Human Antigen T Cell Receptor: Selected Protocols and Applications. Georgetown, TX: R. G. Landes Company 1997, pp 432-459.
- 21. Krangel MS, Buchwalder A, York J, and **Diamond DJ.** Lipid anchored and soluble forms of TCR molecules. In: Oksenberg, J. R. (ed). The Human Antigen T Cell Receptor: Selected Protocols and Applications. Georgetown, TX: R. G. Landes Company 1997, pp 546-631.
- 22. Yu Z, Liu X, McCarty TM, **Diamond DJ**, Ellenhorn JDI: The use of transgenic mice to generate p53 specific and HLA restricted cytolytic T cells (CTL). <u>Journal of Surgical Research</u>, 69: 337-343, 1997.
- 23. **Diamond DJ**, York J, Sun J, Wright C, and Forman SJ. Development of an Candidate HLA A\*0201 restricted peptide-based vaccine against human cytomegalovirus infection. <u>Blood (Rapid Communication)</u>, 90: 1751-1767, 1997.
- 24. McCarty TM, Liu X, Schwarz RE, **Diamond DJ**, and Ellenhorn JDI.

  Targeting p53 for adoptive T cell immunotherapy. <u>Owen H. Wangensteen Surgical Forum</u>, 48,783-785, 1997.

- McCartyTM, Liu X, Sun J, Peralta EA, **Diamond DJ**, and Ellenhorn JDI: Targeting p53 for adoptive T Cell immunotherapy. <u>Cancer Research</u>, 58: 2601-2605, 1998.
- 26. McCarty TM, Yu Z, Liu X, **Diamond DJ**, and Ellenhorn JD. An HLA-restricted p53 specific immune response from HLA transgenic p53 knockout mice. Ann. <u>Surg. Oncol.</u> 5(1):93-99, 1998
- 27. Schwarz RE, McCarty TM, Peralta EA, **Diamond DJ**, and Ellenhorn JDI. An orthotopic in vivo model of human pancreatic cancer. <u>Surgery</u>, 126 (3): 562-567, 1999.
- 28. Peralta E, McCarty TM, Doerr A, Jones PA, Markl I, **Diamond DJ**, and Ellenhorn JDI. Immunotherapy of bladder cancer by targeting p53. <u>Journal of Urology</u>, 162(5):1806-11, 1999.
- 29. Liu X, Peralta E, Ellenhorn J and **Diamond DJ**. Targeting of Human p53-overexpessing Tumor Cells by an HLA A\*0201-restricted Murine T-Cell Receptor Expressed in Jurkat T cells. <u>Cancer Research</u>, 60:693-701, 2000.
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## **Patents**

**Diamond, D.J.** and York, J. Immuno-reactive Peptide CTL Epitopes of Human Cytomegalovirus. Patent # 6,074,645, June 13, 2000

**Diamond, D. J.** and York, J. Immuno-reactive Peptide CTL Epitopes of Human Cytomegalovirus. Patent # 6,156, 637, December 5, 2000

**Diamond, D.J.** Immuno-Reactive Peptide CTL Epitopes of Human Cytomegalovirus. Patent # 6,251,399, June 26, 2001

**Diamond, D.J.** Immunoreactive peptide CTL epitopes of cytomegalovirus pp150. Patent # 6,544,521, April 8, 2003

**Diamond, D.J.** Immuno-Reactive Peptide CTL Epitopes of Human Cytomegalovirus. Patent # 6,562,345, May 13, 2003

Diamond, D.J. CTL Epitope Analogs. Patent # 6,632,435. October 14, 2003.

**Diamond, D.J.** Immuno-Reactive Peptide CTL Epitopes of Human Cytomegalovirus. Patent # 6,726,910, April 27, 2004

**Diamond, D.J.** HCMV-reactive T cells and uses thereof. Patent # 6,727,093, April 27, 2004

**Diamond, D.J.** Diagnostic Reagents for Human Cytomegalovirus and Methods of use. Patent # 6,733,973, May 11, 2004

Ellenhorn, J. and **Diamond, D.J.** p53-specific T Cell Receptor for Adoptive Immunotherapy. Patent # 6,770,749, August 3, 2004

**Diamond, D.J.** Immuno-Reactive Peptide CTL Epitopes of Human Cytomegalovirus. Patent # 6,843,992, January 18, 2005

Diamond, D.J. CTL Epitope Analogs. Patent # 6,951,651, October 4, 2005.

**Diamond, D.J.** Diagnostic reagents for human cytomegalovirus and methods of use. Patent #7,160,685, January 9, 2007.

**Diamond, D.J.** and Wang, Z. Human cytomegalovirus antigens expressed in MVA and methods of use. Patent # 7,163,685, January 16, 2007.

Ellenhorn, J. and **Diamond, D.J.** Modified vaccinia Ankara expressing p53 in cancer immunotherapy. Patent # 7,256,137, August 14, 2007.

## Invited Talks-Selected

- 4/87 Oral presentation of abstract and travel award for the Leukemia Society of America Annual Meeting, Tampa, FL
- 12/95 American Society for Hematology Annual Meeting, Invited speaker oral session, "Molecular Analysis of T-Cell Receptor Repertoire in Bone Marrow Transplant Recipients," Seattle, WA.
- 6/95 Invited Presentation at Baxter Hyland Division, sponsored by Dr. William Landsberger.
- 7/96 Presentation given at Darwin Molecular Corporation, sponsored by John A. Hansen, M.D.
- Oral presentation of abstract at the American Society for Hematology Annual Meeting in Seattle, WA,
- 3/98 Presentation at L.A.C.+U.S.C. Medical Center, Division of Infectious Diseases, sponsored by Dr. John M. Leedom.
- 9/98 Presentation to the Graduate Program in Immunology at Johns Hopkins University Medical Center, sponsored by R. Siliciano, M.D.
- 11/98 Presentation at Children's Hospital, Los Angeles, sponsored by Dr. D. Kohn.
- 12/98 American Society for Hematology Annual Meeting, Invited speaker oral session, "Development of an In Vitro Stimulation (IVS) Protocol to measure CMV Specific CTL Activity Using HLA-Restricted Specific CTL Epitopes," Miami Beach, FL.
- 1/99 Invited presentation at Frederick Cancer Research and Development Center, sponsored by Dr. Edward Sausville, Developmental Therapeutics Program, NCI.
- 12/99 American Society for Hematology Annual Meeting, Invited speaker oral session, "Induction of CTL Response by a Minimal Epitope Vaccine in HLA A\*0201/DR1 Transgenic Mice: Dependence on HLA Class II Restricted T<sub>H</sub> Response," New Orleans, LA.
- 10/00 3<sup>rd</sup> Annual Vaccine Conference at the CDC, Invited speaker Atlanta, Georga
- 11/00 Invited presentations at University of Tubingen (Dr. Hermann Einsele) University of Mainz (Dr. Bobo Plachter) Max Planck, Berlin (Dr. Hans Lehrach).
- 12/00 42th Meeting of the American Society for Hematology, Invited speaker "Education Session", San Francisco, CA
- 12/00 Invited presentation at Frederick Cancer Research and Development Center, sponsored by Dr. Edward Sausville, Developmental Therapeutics Program, NCI.
- 5/01 8<sup>th</sup> CMV Workshop at Asilomar Conference Center, 3 Oral Presentations. 5<sup>th</sup> ASGT Annual Meeting, Invited Symposia Speaker "HIV Vaccines".
- 8/02 Invited speaker to ACS 224<sup>th</sup> Annual Meeting, "Advances in Vaccine Development Session", Boston, MA.
- Oral presentation at 9<sup>th</sup> CMV workshop (given by Dr. Zhongde Wang) in Maastricht, Holland. "Recombinant MVA Expressing Soluble CMV-gB Induces Durable CMV-Neutralizing Antibodies"

7/03	Invited Seminar at LIAI, La Jolla, CA. "Poxviruses as Tools in Herpesvirus,
8/03	HIV, and Cancer Vaccine Development."  Invited speaker at NCI-Frederick, "Biopharmaceutical Development
12/03	Program Retreat 2003."  American Society for Hematology Annual Meeting, Invited speaker oral session, "Attenuated Poxvirus Expressing Multiple CMV Antigens is a Highly Efficient Means to Elicit Human CD8 T Lymphocytes Suitable for Adoptive Immunotherapy or Donor Immunization," San Diego, CA.
8/04	Invited Presentation at Queensland Institute of Medical Research (Brisbane, Australia)
10/04	Invited Presentation for Developmental Therapeutics Program of the National Cancer Institute on awarded RAID project, "GMP manufacturing Strategy for p53-MVA" (Frederick, MD)
11/04	Invited Presentation for Cancer Center Grand Rounds at Norris Comprehensive Cancer Center, University of Southern California (Los Angeles, CA)
02/05	Invited Seminar, Mayo Clinic, Department of Medicine, TIB Program (Rochester, MN)
04/05	Invited Plenary Talk at the 10 <sup>th</sup> Biennial Betaherpesviridae Workshop, (Williamsburg, VA)
04/05	Invited Speaker, Virginia Commonwealth University (Richmond, VA)
05/05	Invited Speaker, Mt. Sinai School of Medicine, Emerging Pathogens, Division of Infectious Diseases (New York, NY)
12/05	Parallel Session Short Oral Presentations, American Society for Hematology Annual Meeting, Session: Infectious Complications after Stem Cell Transplantation II, "Development and Immunologic Characterization of Multi-Antigen Expressing Attenuated Poxviruses for Immunotherapy of CMV Infection in HSCT Recipients," and "Peptide Libraries to CMV Antigens Predict Levels of Cytotoxic Function of CMV-specific CTL Populations in PBMC fro HSCT Recipients,", Atlanta, GA.
3/06	Invited Presentation, Cancer Center Seminar Series, Comprehensive Cancer Center, University of Alabama, Birmingham, AL
5/06	Invited Speaker, Harvard Medical School, Dana-Farber Cancer Institute, Department of Adult Oncology
5/06	Invited Speaker, Coley Pharmaceutical Group, Wellesley, MA
6/06	Invited Speaker, University of California (Davis), Center for Comparative Medicine, Davis, CA
9/06	Invited Speaker, University of Minnesota School of Dentistry
10/06	Oral Abstract Presentation, "Nature Bench to Bedside Conference", La Jolla, CA
11/06	Invited Speaker, "Conference on Congenital CMV infection", Orvieto, Italy.
03/07	Invited speaker to 3 <sup>rd</sup> Annual AlloStem Meeting, Presentations on the topics, "Vaccines and Immune Monitoring", Hospital Saint Louis, Paris.
05/07	Invited Speaker to 12 <sup>th</sup> Annual UCLA Human Gene Medicine Symposium, Los Angeles, CA
06/07	Invited Presentation (Dr. Martin Kast) at Norris Comprehensive Cancer

Center, University of Southern California (Los Angeles, CA)

Invited Speaker to Waldthausen Castle Symposium on Cytomegalovirus,

Over view lecture, "Novel Approaches to Vaccines", Mainz, FRG

## Consultantships

11/07

8/95 - Baxter Hyland Division, "IVIG"/Immunomodulation Technical Focus" Meeting, sponsored by Dr. D. Baker/W. Landsberger, Dr. R. Lundblad.